MEDSHAPE
SOLUTIONS

JUN 10 2011

Special 510(k) Summary

Special 510(k) Number: K111471

Date Prepared: May 26, 2011

This Special 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
MedShape Solutions, Inc. (**MSS**)
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Atlanta, Georgia 30318
Registration #10026693

B. Company Contact:
Jack Griffis
Vice President, Research & Development
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C. Device Information:
Trade Name: *ExoShape*™-XL Interference Fixation Device
Common Name: Fastener, Fixation, bone, non-degradable

D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
HWC/MBI 21 CFR 888.3040

E. Predicate Device(s):
MSS, *ShapeLoc* Interference Fixation Device, K101808
Parcus Medical PEEK CF Interference Screw, K091093
Arthrex® Interference Screw, K062466

F. Labeling and Intended Use:

No substantive changes to the labeling or Instructions for Use have been made to the submitted information of the MedShape predicate per K101808.

The proposed *ExoShape*™-XL Interference Fixation Device has the same intended uses as the previously cleared predicate device per K101808. As such, both devices are indicated for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Anchiles Tendon Reconstruction and Tendon Transfers

Knee:	Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and Repairs and Tendon Transfers
Elbow:	Biceps Tendon Reattachment and Ulnar or Radial collateral Ligament Reconstruction

G. Substantial Equivalence Summary:

The *ExoShape*™-XL Interference Fixation Device is a line extension offering additional sizes within the current cleared product line and is substantially equivalent to the *ShapeLoc* (original product name) Soft Tissue Fastener, cleared under K101808. The technological characteristics of the *ExoShape*™-XL and the *ShapeLoc* Interference Fixation Devices are equivalent. It is important to note that the *ShapeLoc* product name was changed to *ExoShape*™ after clearance, and the two names are considered interchangeable.

In addition, the *ExoShape*™-XL is substantially equivalent to the original predicate Arthrex® Interference Screw, cleared under K062466 and the additional predicate Parcus Medical PEEK CF Interference Screw, cleared under K091093. Any differences between the *ExoShape*™-XL Interference Fixation Device and the listed predicates *ShapeLoc*, Arthrex® or Parcus Medical Interference Screw Devices are considered minor and do not raise questions concerning safety and effectiveness.

Functional performance testing was conducted in both Sawbone® and porcine bone analogues. This testing included monotonic soft tissue fixation strength and other dimensional verification. Analysis of the results supports the conclusion that the proposed device is substantially equivalent to the listed devices. Based on the information submitted, MedShape Solutions, Inc. has determined that the proposed *ExoShape*™-XL Interference Fixation Device is substantially equivalent to the currently marketed device.

Jack Griffis
Vice President, Research & Development

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MedShape Solutions, Inc (MSS)
% Mr. Jack Griffis
Vice President, Research & Development
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

JUN 10 2011

Re: K111471
Trade/Device Name: ExoShape™-XL Interference Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: May 26, 2011
Received: May 27, 2011

Dear Mr. Griffis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: *ExoShape*™-XL Interference Fixation Device

Indications for Use:

The MedShape Solutions, Inc., *ExoShape*™-XL Interference Fixation Device is intended for fixation of soft tissue to bone in the following procedures:

Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Anchiles Tendon Reconstruction and Tendon Transfers
Knee:	Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and Repairs and Tendon Transfers
Elbow:	Biceps Tendon Reattachment and Ulnar or Radial collateral Ligament Reconstruction

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Erin D. Keith

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111471

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